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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,955	10/28/2003	Robert Naylor Laurie	P07351US01/BAS	3799
881 7590 03/04/2009 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 03/04/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/693,955

Applicant(s)

LAURIE ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3, 4, 10, 13 and 15 is/are allowed.
- 6) ☒ Claim(s) 8, 11, 12, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. §1.114, the Amendment and Applicant's Arguments/Remarks, all filed 12/15/08 and the Notice of Appeal filed 10/15/08 is acknowledged.

The 35 U.S.C. §112, first paragraph rejection of claims 1, 3, 4, 8, 10 and 12 has been withdrawn by virtue of the amendment to the claims. This rejection is maintained for claim 11.

Claims 1, 3, 4, 8 and 10-16 are pending in this action. Claims 1, 3 and 10-12 have been amended. New claims 15 and 16 have been added. Claims 2, 5-7 and 9 have been cancelled. Claims 1, 3, 4, 10, 13 and 15 are allowable. Claims 8, 11, 12, 14 and 16 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 December 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 recites that the “trace element solution comprises a metal concentration of at least 60 mg/ml”. The limitation of a metal concentration comprising “at least 60 mg/ml” introduces new matter into the instant claims. Applicant has not provided ample support for the claim language. A review of the instant specification indicates that all of Examples 1-7 permits ranges *less than* 60 mg/ml of metal concentration. The fact that an example has 60 mg/ml does not establish that, at the time of the invention, Applicant was aware that the use of “at least 60 mg/ml”, which has a scope well above 60, was a critical lower limit for their claimed invention. There is no specific teaching to combine Examples 6 and 7 of the instant specification. Thus, the claim language reciting “at least 60 mg/ml” of a metal concentration introduces a new concept not disclosed in the original specification.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (U.S. Patent No. 4,335,116).

Howard ('116) teaches stable mineral-containing therapeutic compositions in the form of aqueous solutions for parenteral administration to domesticated animals, such as livestock. The compositions comprise water-soluble organometallic complexes of ions of zinc, copper, manganese, chromium and selenium and including at least two organic, metal-ion-complexing agents. Methods for restoring and/or maintaining normal micromineral-dependent metabolic

function, increasing feed intake, increasing vigor and facilitating resistance to infectious disease comprising administering the solutions to domesticated animals is also disclosed (see Abstract); (col. 4, line 51 – col. 5, line 5).

Solutions may be prepared to provide from about 0.1 to about 25 mg of *zinc*; from about 0.1 to about 10 mg of *copper*; from about 0.1 to about 20 mg of *manganese*; from about 0.01 to about 5.0 mg of *chromium*; and from about 0.1 to about 12.0 mg of *selenium* (col. 5, lines 26-35); (Claim 1). These mineral amounts are equivalent to 72 mg/ml of the combined zinc, copper, manganese, chromium and selenium components. Thus, the “72 mg/ml” metal concentration of Howard reads on Applicant's metal concentration of “60 mg/ml” recited in instant claims 11 and 16.

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Howard. Howard explicitly teaches mineral-containing solutions formulated for domesticated animals (i.e., livestock) whereby the solutions are comprised of various minerals that necessarily include zinc, copper, manganese, chromium and selenium. These minerals are provided in effective amounts to yield a total concentration that is greater than 60 mg/ml as is claimed by Applicant. The solutions are useful for parenteral administration and thus read on the “injectable solution” as claimed.

* * * * *

Response to Arguments

Applicant's arguments filed 12/15/08 have been fully considered and were found to be partially persuasive.

▪ **Rejection under 35 U.S.C. 112, first paragraph:**

Applicant argued, “Applicants have amended claims 1 and 12 to remove reference to the ‘at least 60 mg/ml’ concentration, thereby obviating the new matter/written description rejection.”

Applicant’s arguments were found persuasive by virtue of the amendment to the claims. Accordingly, the 35 U.S.C. §112, first paragraph rejection of claims 1, 3, 4, 8, 10 and 12 has been withdrawn. However, this rejection has been maintained as it applies to claim 11, which still recites “at least 60 mg/ml”. Support for “*at least*” 60 mg/ml has not been established.

* * * * *

Allowable Subject Matter

Claims 1, 3, 4, 10, 13 and 15 are allowed.

Claim 8 would be allowable if Applicant overcomes the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

* * * * *

Conclusion

Claims 8, 11, 12, 14 and 16 are rejected.

Claims 1, 3, 4, 10, 13 and 15 are allowable.

Claims 2, 5-7 and 9 are cancelled.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

February 27, 2009

